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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/646,939	11/14/00	MULROONEY	C	7145-100

HM12/0214

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EXAMINER

CHUNDURU, S

ART UNIT

PAPER NUMBER

02/14/01  
DATE MAILED: 2

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/646,939	MULROONEY, CONOR
	Examiner	Art Unit
	Suryaprabha Chunduru	1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 November 2000.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) Notice of References Cited (PTO-892)      18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)      19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      20) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Preliminary Amendment (Paper No. 6) filed on November 14, 2000 has been entered and considered.
2. The disclosure is objected because of the following informalities:

***Specification***

(i) The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

**Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraiser et al (USPN. 5,648,211) and in view of Cleuziat et al. (USPN. 5,824,517).

Fraiser et al. teach Strand Displacement Amplification (SDA) method wherein they disclose that the method was performed isothermally (see column 3, lines 8-12 and column 4, lines 4552); the 3' end of the amplification primer (target binding sequence) hybridizes at the 3' end of the target sequence (see column 3, lines 46-58). The method involves binding of amplification primers to an original target sequence or a displaced single-stranded extension product, extension of the primers by a 5'-3' exonuclease deficient polymerase incorporating an  $\alpha$ -thiol deoxynucleoside triphosphate nicking of a hemimodified double stranded restriction site, dissociation of the restriction enzyme from the nick site and extension from the 3' end of the nick by the 5'-3' exonuclease deficient polymerase with displacement of the downstream newly synthesized strand (see column 4, lines 65-67 and column 5, lines 1-8). The exonuclease deficient polymerases include exo<sup>-</sup> Vent, exo<sup>-</sup> Deep Vent, Bst, and exo<sup>-</sup>Pfu (see column 7, lines 11-18). The cleavage of one of the two strands in the duplex of the cleavage site is selectively inhibited by introducing nucleotide analogs (e.g, deoxynucleoside phosphorothioates) into one strand of the DNA during synthesis so that the modified strand no longer susceptible to cleavage (see column 7, lines 40-54). The primers used in examples (1 and 4) were 30-mer, 58-mer and 81-mer oligonucleotides (see column 9, lines 56-59 and column 17, lines 5-9). However they did not disclose T7 Gene 6

exonuclease, performing two separate reactions by removal of enzyme between steps and multiplex or nested amplification of the target sequence with third and fourth primers.

Cleuziat et al. teach an isothermal method of amplification of a target nucleic acid (RNA and /or DNA) wherein they disclose placing a DNA-type single stranded polynucleotide in contact, in the presence of an enzyme with DNA-dependent DNA polymerase activity, strand displacement activity and RNase H activity and in the presence of excess deoxyribonucleotide triphosphates, with a set of primers (see column 6, lines 28-67 and column 1-30). Further they disclose use of third, fourth, fifth and sixth primers for the segments, regions or zones of the target polynucleotide that may hybridize with these primers or primer segments (see column 7, lines 44-58). The DNA polymerase with no exonuclease 5'-3' activity used in this method include Klenow fragment of Escherichia coli DNA polymerase, T7 DNA polymerase or sequenase (see column 9, lines 48-69). The amplified products can be separated from enzymes used for amplification so as to use them in later processes involving other enzymatic reactions (see column 14, line 67 and column 15, lines 1-4).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention was made to combine a method of Strand Displacement Amplification with multiplex primer method to achieve the claimed invention as whole for the expected advantage of producing copies of nucleic acids. The motivation for this would have been an approach to detect multiple sites of target nucleic acid in a reaction and obtaining multiple copies of the same by amplification process. Any inquiry

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concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Margaret M Parr can be reached on 703-308-2454. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*gpe*  
Suryaprabha Chunduru  
February 12, 2001



EGGERTON A. CAMPBELL  
PRIMARY EXAMINER